AMENDMENTS TO THE SPECIFICATION:

Please amend the last, partial paragraph on page 3, beginning at line 21, as follows:

In accordance with a first embodiment of the invention, the property improving means comprises a coating on the base material at least along a side of the elongate composite structure that is intended to contact the stomach or esophagus, wherein the coating has better aggressive body fluid resistance than the base material. Such a coating may comprise a Teflon™ tetrafluoroethylene polymer or Parylene™ poly-para-xylylene polymer coating, or a biocompatible metal coating such as gold, silver or titanium. ~~As a result, the constriction device can be protected from damaging influences of aggressive body fluids, possibly for the rest of the patient's life.~~

Please delete the first and second, full paragraphs on page 4, beginning at lines 5 and 12, respectively.

Please amend the third, partial paragraph, on page 4, beginning at line 15, as follows:

In one alternative to the first embodiment, the elongate composite structure is designed for mechanical adjustment, such as the mechanical solutions disclosed in International Application No. WO 01/45486. In this altemative, the property improving means comprises a core of a soft viscoelastic material, such as silicone gel, ~~typically~~

~~having a hardness less than 20 Shure,~~ cellulose gel or collagen gel. ~~Where silicone gel is chosen, it may be "Med 3-6300" manufactured by Nusil.~~ Hard silicone constitutes the base material, ~~typically having a hardness of at least 60 Shure,~~ and covers the soft core of viscoelastic material. ~~The soft core makes the implanted elongate composite structure less injurious to the stomach or esophagus, and reduces the injury of such organs. Furthermore, the soft core of viscoelastic material may be formed to enclose and protect mechanical adjustment components and other components of the composite structure, whereby fibrosis is prevented from growing into such components.~~

Please amend the first, full paragraph on page 5, beginning at line 2, as follows:

In another alternative to the first embodiment, the elongate composite structure is designed for hydraulic adjustment, such as the hydraulic solutions disclosed in International Application No. WO 01/50833. In this alternative, the base material forms a closed tubing, which can be inflated by adding hydraulic fluid to the interior of the tubing and deflated by withdrawing hydraulic fluid from the interior of the tubing. The coating of Teflon™ tetrafluoroethylene polymer, Parylene™ poly-para-xylylene polymer or metal may cover the inner surface of the tubing. The base material may form two coaxial tubular layers of hard silicon, and the property improving means may comprise a tubular intermediate layer of a soft viscoelastic material located between the coaxial tubular layers. Alternatively, the base material may form an outer tubular layer and an inner arcuate layer attached to the outer tubular layer, the outer and inner layers defining a

curved space extending longitudinally along the tubing. The property improving means may comprise a viscoelastic material filling the space. The tubing is applied around the stomach or esophagus so that the space with viscoelastic material is located closest to the stomach or esophagus. The viscoelastic material gives the advantages that erosion of the stomach or esophagus is reduced and the risk of hydraulic fluid leaking from the tubing is decreased.

Please amend the third, partial paragraph on page 5, beginning at line 18, as follows:

In accordance with a second embodiment of the invention, the base material forms a first layer and the property improving means comprises a second layer applied on the first layer, wherein the second layer is more fatigue resistant than the first layer. The first layer preferably is comprised of hard silicone, whereas the second layer preferably is comprised of a polyurethane layer. ~~In a traditional silicone band, especially the tubular type, that is formed in a loop to constrict the stomach or esophagus, the inner surface of the band loop that contacts the stomach or esophagus forms bulges and creases that repeatedly change as the band is subjected to dynamic movements from the stomach or esophagus and when the size of the band is adjusted. As a consequence, the implanted traditional silicone band has the drawback that it may crack after some time due to fatigue of the silicone material.~~ With the elongate composite structure of the invention, in which hard silicone may constitute the base material and a fatigue resistant

polyurethane layer covers the silicone material on the side of the elongate composite structure that contacts the stomach or esophagus, the drawback is eliminated.

Please delete the first and second, full paragraphs on page 6, beginning at lines 8 and 14, respectively.

Please amend the third, full paragraph on page 6, beginning at line 16, as follows:

In accordance with a third embodiment of the invention, the base material forms an inflatable tubing and the property improving means comprises a liquid impermeable coating coated on the base material. The coating may be coated on the external and/or internal surface of the tubing. Preferably, the liquid impermeable coating comprises a Parylener™ poly-para-xylylene polymer coating, or a biocompatible metal coating. Where hard silicone, which is a liquid semi-permeable material, constitutes the base material, the coating of Parylene™ poly-para-xylylene polymer or metal gives the advantage that the tubing may be inflated by hydraulic fluid under pressure without risking fluid diffusing through the silicone wall of the tubing.

Please amend the first, full paragraph on page 7, beginning at line 8, as follows:

In accordance with a fourth embodiment of the invention, the property improving means comprises gas, such as air, contained in a multiplicity of cavities formed in the base material to improve the flexibility of the composite structure. In this case, Teflon™

tetrafluoroethylene polymer advantageously constitutes the base material. The cavities may be defined by net structures of the Teflon™ tetrafluoroethylene polymer material. Thus, the resulting composite structure of Teflon™ tetrafluoroethylene polymer and cavities filled with gas is strong, flexible and aggressive body fluid resistant, and has good tensile strength and good anti-friction properties. Also, in the fourth embodiment, the elongate composite structure may comprise an inflatable tubing.

Please amend the second, full paragraph on page 7, beginning at line 16, as follows:

The present invention also provides an implantable constriction device for treating an incontinent patient, comprising an elongate composite structure adapted to constrict the stomach or esophagus of the patient, wherein the composite structure includes an elongate biocompatible self-supporting base material having surfaces exposed to aggressive body cells, when the constriction device is implanted in the patient, and a cell barrier coating on the surfaces to prevent body cells from breaking down the base material, which is typically silicone. ~~If the base material were broken down by such body cells, typically macrophages or killer cells, histological particles would be spread in the human body.~~

Please amend the last, partial paragraph on page 7, beginning at line 25, as follows:

The barrier coating may comprise Parylene™ poly-para-xylylene polymer coating or a biocompatible metal coating.

Please amend the first, full paragraph on page 8, beginning at line 2, as follows:

Alternatively, the barrier coating may comprise a composite of different materials to achieve the cell-barrier protection as described above. There are several examples of such composite materials on the market, for example an ~~composite of polyurethane and silicone called~~ Elaston™ polyurethane silicone composite.

Please add the following paragraphs after the heading "detailed Description of the Drawings":

Accordingly, the present invention provides an implantable constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient, the constriction device comprising an elongate composite structure adapted to constrict the stomach or esophagus to form the stoma opening therein, wherein the elongate composite structure is composed of a base material making the composite structure self-supporting and property improving means for improving at least one physical property of the composite structure other than self-supporting properties.

In accordance with a first embodiment of the invention, the property improving means comprises a coating on the base material at least along a side of the elongate composite structure that is intended to contact the stomach or esophagus, wherein the

coating has better aggressive body fluid resistance than the base material. Such a coating may comprise a Teflon™ tetrafluoroethylene polymer tetrafluoroethylene polymer or Parylene™ poly-para-xylylene polymer poly-para-xylylene polymer coating, or a biocompatible metal coating such as gold, silver or titanium.

In one alternative to the first embodiment, the elongate composite structure is designed for mechanical adjustment, such as the mechanical solutions disclosed in International Application No. WO 01/45486. In this altemative, the property improving means comprises a core of a soft viscoelastic material, such as silicone gel, cellulose gel or collagen gel. Hard silicone constitutes the base material, and covers the soft core of viscoelastic material. The soft core makes the implanted elongate composite structure less injurious to the stomach or esophagus, and reduces the injury of such organs. Furthermore, the soft core of viscoelastic material may be formed to enclose and protect mechanical adjustment components and other components of the composite structure, whereby fibrosis is prevented from growing into such components.

In another alternative to the first embodiment, the elongate composite structure is designed for hydraulic adjustment, such as the hydraulic solutions disclosed in International Application No. WO 01/50833. In this alternative, the base material forms a closed tubing, which can be inflated by adding hydraulic fluid to the interior of the tubing and deflated by withdrawing hydraulic fluid from the interior of the tubing. The coating of Teflon™, Parylene™ poly-para-xylylene polymer or metal may cover the inner surface of the tubing. The base material may form two coaxial tubular layers of hard

silicon, and the property improving means may comprise a tubular intermediate layer of a soft viscoelastic material located between the coaxial tubular layers. Alternatively, the base material may form an outer tubular layer and an inner arcuate layer attached to the outer tubular layer, the outer and inner layers defining a curved space extending longitudinally along the tubing. The property improving means may comprise a viscoelastic material filling the space. The tubing is applied around the stomach or esophagus so that the space with viscoelastic material is located closest to the stomach or esophagus. The viscoelastic material gives the advantages that erosion of the stomach or esophagus is reduced and the risk of hydraulic fluid leaking from the tubing is decreased.

In accordance with a second embodiment of the invention, the base material forms a first layer and the property improving means comprises a second layer applied on the first layer, wherein the second layer is more fatigue resistant than the first layer. The first layer preferably is comprised of hard silicone, whereas the second layer preferably is comprised of a polyurethane layer. With the elongate composite structure of the invention, in which hard silicone may constitute the base material and a fatigue resistant polyurethane layer covers the silicone material on the side of the elongate composite structure that contacts the stomach or esophagus, the drawback of cracking over time due to fatigue of the silicone material is eliminated.

In accordance with a third embodiment of the invention, the base material forms an inflatable tubing and the property improving means comprises a liquid impermeable coating coated on the base material. The coating may be coated on the external and/or

internal surface of the tubing. Preferably, the liquid impermeable coating comprises a Parylener™ coating, or a biocompatible metal coating. Where hard silicone, which is a liquid semi-permeable material, constitutes the base material, the coating of Parylene™ poly-para-xylylene polymer or metal gives the advantage that the tubing may be inflated by hydraulic fluid under pressure without risking fluid diffusing through the silicone wall of the tubing.

Also, in the third embodiment, the base material may form two coaxial tubular layers of hard silicon, and the property improving means may comprise a tubular intermediate layer of a soft viscoelastic material located between the coaxial tubular layers. Alternatively, the base material may form an outer tubular layer of hard silicone and an inner arcuate layer of silicone attached to the outer tubular layer. The outer and inner layers define a curved space extending longitudinally along the tubing and filled with the viscoelastic material. The tubing is intended to be applied around the stomach or esophagus so that the space with viscoelastic material is located closest to the stomach or esophagus.

In accordance with a fourth embodiment of the invention, the property improving means comprises gas, such as air, contained in a multiplicity of cavities formed in the base material to improve the flexibility of the composite structure. In this case, Teflon™ tetrafluoroethylene polymer advantageously constitutes the base material. The cavities may be defined by net structures of the Teflon™ tetrafluoroethylene polymer material. Thus, the resulting composite structure of Teflon™ tetrafluoroethylene polymer and

cavities filled with gas is strong, flexible and aggressive body fluid resistant, and has good tensile strength and good anti-friction properties. Also, in the fourth embodiment, the elongate composite structure may comprise an inflatable tubing.

The present invention also provides an implantable constriction device for treating an incontinent patient, comprising an elongate composite structure adapted to constrict the stomach or esophagus of the patient, wherein the composite structure includes an elongate biocompatible self-supporting base material having surfaces exposed to aggressive body cells, when the constriction device is implanted in the patient, and a cell barrier coating on the surfaces to prevent body cells from breaking down the base material, which is typically silicone. The barrier coating may comprise a Parylene™ poly-para-xylylene polymer coating or a biocompatible metal coating. Alternatively, the barrier coating may comprise a composite of different materials to achieve the cell-barrier protection as described above. There are several examples of such composite materials on the market, for example a Elaston™ polyurethane silicone composite.

Please amend the first, partial paragraph after the heading "Detailed Description of the Drawings" on page 8, beginning at line 18, as follows:

Figure 1 illustrates a mechanical constriction device 2 according to the invention comprising an elongate composite structure 4 adapted to extend around and constrict the stomach or esophagus of a patient to form a restricted stoma opening therein. Referring to

Figure 2, the elongate composite structure 4 comprises a strong band 6 of nylon or the like, a tubular layer 8 of hard silicone, in which the band 6 slides, a soft layer 10 of a viscoelastic material, here a silicone gel having a hardness not more than 20 Shure, encircling the hard silicone layer 8, and a tubular layer 12 of a self-supporting base material of hard silicone having a hardness of at least 60 Shure, surrounding the soft silicon layer 10. A coating 14 of Teflon™ tetrafluoroethylene polymer, Parylene™ poly-para-xylylene polymer or a biocompatible metal, such as gold, silver or titanium, is coated on the outer hard silicone layer 12 to make the composite structure resistant to aggressive body fluids and to give the composite structure good anti-friction properties. A coating of Teflon™ tetrafluoroethylene polymer, Parylene™ poly-para-xylylene polymer or metal may also be coated on the internal surface of the inner tubular hard silicone layer 8 to reduce the friction between the nylon band 6 and the layer 8. The constriction device 2 has an adjustment means 16 that can displace the end portions of the nylon band 6 relative to each other to either enlarge or constrict the stoma opening.

Please amend the first, full paragraph on page 9, beginning at line 16, as follows:

Figure 4 shows a cross-section of an elongate composite structure 22 of an embodiment of the invention, in which Teflon™ tetrafluoroethylene polymer constitutes the self-supporting base material, which is formed with a longitudinal cavity in which a strong nylon band 24 slides. Property improving means in the form of gas, here air,

contained in a multiplicity of cavities 26 are formed in the base material to improve the flexibility thereof.

Please amend the last, partial paragraph on page 9, beginning at line 21, as follows:

Figure 5 shows a hydraulic constriction device 28 according to the invention comprising an elongate composite structure in the form of an inflatable tubing 30, in which the base material of hard silicone forms an outer tubular layer 32 and an inner coaxial layer 34. A viscoelastic material, here soft silicone gel, forms an intermediate layer 36 located between the tubular layers 32,34. Four longitudinal partition walls 38 between the tubular layers 32,34 divide the intermediate layer 36 into four sections to prevent the silicone gel from displacing in the circumferential direction of the tubing 30. (Also the embodiments according to Figures 2 and 3 may be provided with such longitudinal partition walls.) The outer layer 32 is coated with a coating 40 of Teflon™ tetrafluoroethylene polymer, Parylene™ poly-para-xylylene polymer or metal. Also the inner layer 34 may be coated with a coating of Teflon™ tetrafluoroethylene polymer, a Parylene™ poly-para-xylylene polymer or metal. If a poly-para-xylylene polymer Parylene™ or metal coating is chosen the composite structure will be completely liquid impermeable.

Please amend the first, full paragraph on page 11, beginning at line 1, as follows:

Figure 8 shows a cross-section of an elongate composite structure 48 of an embodiment of the invention, in which Teflon™ tetrafluoroethylene polymer constitutes the self-supporting base material, which is formed to an inflatable tubing 50. Property improving means in the form of gas contained in a multiplicity of cavities 26 are formed in the base material to improve the flexibility of the tubing 50.

Please amend the second, full paragraph on page 11, beginning at line 6, as follows:

Figure 9 shows a cross-section of a tubular composite structure of an embodiment of the invention, in which the self-supporting base material 52 is made of a polymer material suited for implantation, for example silicone or polyurethane. A property improving coating 54, for example made of Parylene™ poly-para-xylylene polymer, Teflon™ tetrafluoroethylene polymer or metal, is applied on the external surface or on both the external and internal surfaces of the tubular structure

Please amend the fourth, full paragraph on page 11, beginning at line 14, as follows:

Figure 11 shows a cross-section of a mechanical constriction device of another embodiment of the invention, comprising a double walled tubing 60 of a self-supporting base material of hard silicone. The tubing 60 has an external wall 62 and an internal wall 64 spaced from the external wall 62,partition walls 66 dividing the space between the

external and internal walls 62 and 64, respectively, of the tubing 60 into longitudinal cells 68, which are filled with a soft viscoelastic material, for example silicone gel. The internal wall 64 is coated with a friction reducing coating 70, for example made of Teflon™ tetrafluoroethylene polymer or the like. A strong band 72 of nylon or the like slides in the tubing 60 on the friction reducing coating 70 to enable adjustment of the constriction device in the same manner as described above in connection with the embodiment according to Figures 1 and 2.